REMARKS/ARGUMENTS

Claims 1-35 and 37-42 are pending in this application. Claim 1 has been amended to more clearly define the subject matter for which the applicants are seeking patent protection. The amendment incorporates the subject matter recited in original claims 2 and 6 into claim 1. Accordingly, claims 2 and 6 have been canceled without prejudice or disclaimer. Furthermore, claims 3 and 7 have been amended to change their dependency from claims 2 and 6, respectively, to claim 1, i.e., due to the cancellation of claims 2 and 6. No new matter is added by any of the changes discussed above, which are all entirely supported by the application as originally filed. Entry of the claim amendments is, therefore, respectfully solicited since the claim amendments and remarks presented herein are believed to place the entire application in condition for an allowance or, at a minimum, to materially reduce the issues for an appeal. Upon such entry, claims 1, 3-5, 7-35 and 37-42, as amended, will be pending in this application.

The present Office Action maintains the claim rejections originally set forth in the previous Office Action dated June 2, 2008, i.e., the claims are again rejected for "obviousness" under 35 U.S.C. §103 over the combination of Kropf et al. DE 10063945 A1 in view of USP 5,980,955 to Greenberg et al. The subject references are discussed in detail in applicants' Amendment in response to the June 2, 2008 Office Action, dated September 22, 2008 and those remarks are expressly incorporated herein by reference.

As indicated above, in response to the rejections as set forth in the Office Action, applicants have amended claim 1, i.e., the only independent claim, of this application such that the claim as amended now recites:

> A chewing gum coated by at least one layer, said layer comprising a coating material which is a composite of a slightly water-soluble calcium salt and a protein component, which salt is selected from the group consisting of fluoroapatite, carbonate-containing nonstoichiometric apatite, hydroxyapatite and fluorine-doped hydroxyapatite, wherein the slightly water-soluble calcium salt has a particle size less than 1000 nm.

Claim 1 as amended is believed to completely distinguish applicants' chewing gum from the combination of Kropf et al. and Greenberg et al. for the reasons presented below. Furthermore, all of the other claims pending in this application depend directly or indirectly from claim 1. Thus they contain all of the recitations found in the subject claim and they are believed to be distinguishable for the same reasons as independent claim 1.

The Kropf et al. ("Kropf") reference discloses poorly soluble calcium salts, such as hydroxyapatite or fluoroapatite, preferably provided in combination with a protein. According to paragraph [0018] of US 2003/0219388 (Kropf), the proteins serve as protective colloids, which are adsorbed onto the surface of the nano particles to prevent them from coagulating and agglomerating, as well as for slowing the crystal growth. Kropf, however, does not disclose to use the composites disclosed thereby in the coating layer of a chewing gum. Kropf, in fact, specifically relates to the provision of adhesive films suitable for application onto the surface of a tooth. Such adhesive films are (see, e.g., ¶10 of the reference) particularly adapted for embodiment as support films consisting of a solid flexible material, which is soluble or swellable in water, and which is preferably a polymer. According to paragraph [0013] of the reference, the preparation of the support films is conventional, in particular by the preparation of a solution of the polymer and dissolving or dispersing the active compound, in this case the composite, in the solution (see, e.g., ¶13 and ¶¶87-90). Accordingly, a dispersion of the calcium salt /composite material is put into an alcoholic polymer solution and the resultant dispersion is thereafter dried in order to form the adhesive film.

In contrast to the methodology as outlined above, the calcium salt/protein composite recited in, e.g., claim 1 of the present application is employed as a coating layer of a chewing gum. Both the composition of the coating layer and the method by which it is prepared and applied to a chewing gum center differ significantly from the method of preparation of a dental film as disclosed in the Kropf reference. The dental film (Kropf) is prepared by simply mixing the polymer component, e.g., polyvinyl acetate or gelatine hydrolysate, with the active component in an alcohol solution, and then drying the liquids so as to obtain the resultant film. In contrast to the dental film of Kropf, the coating layer as recited, e.g., in claim 1, does not employ an alcohol solution, it does not employ polymer components and it is not just obtained by

drying. As explained below in greater detail, applicants' claimed coating layer (see, e.g., claim 1) is prepared by a complex preparation process according to which under controlled agitation components able to form a crystal layer on a chewing gum core are applied in liquid form to the core, after which they are dried. This sequence of process steps is then repeated a plurality of times. The process, therefore, for preparing the presently claimed chewing gum (e.g., as in claim 1) requires recrystallization of the components applied to the chewing gum center. It does not employ a non-crystallizing step of embedding in a polymer matrix, as taught in Kropf. It does, however, in contrast to Kropf, require adhesion of the coating material onto a core, i.e., wherein the core is formed of different material than the composition used in the coating. Additionally, in the case of the application of multiple coating layers, the composition and method of making the same as used to coat the chewing gum of, e.g., applicants' claim 1, must also permit the coating material to adhere to itself, i.e., when a layer of the coating material is applied to an underlying coating layer. As a result of these differences in composition and method(s) of making, the coating material used in producing applicants' claimed gum has significantly different properties than the formulation described in Kropf et al. That is, the forumlations recited for use in applicants' claims exhibit very different characteristics from the dental film produced according to Kropf, e.g., with respect to their organoleptic properties, their storage properties, and so on. It would, thus, not be simply 'obvious', as alleged by the Examiner, to take a teaching that is applicable to a dental film (Kropf) and apply it to the formation of a chewing gum coating, i.e., since (as discussed above) the products and their method(s) of preparation are entirely different, one from the other.

Turning, next, to a discussion of Greenberg et al. ("Greenberg"), the subject reference is in the field of coatings for chewing gum. As noted in the previous response filed in this case, Greenberg discloses the use of a small quantity of food-acceptable poorly water-soluble salt to improve the smoothness of the finished coating. Accordingly, the reference teaches to use a specific salt, identified in Example 1 as calcium gluconate. The salt is added to a coating syrup comprising xylitol, titanium dioxide, water and gum tahla solution. According to the teaching contained in Greenberg, but also according to the general knowledge expected of an artisan having ordinary skill in this field of art, the coating syrup is then applied under controlled

conditions of temperature, time and mechanical agitation, to the chewing gum core, whereby specific coating and intervening drying times are subsequently utilized. The coating process is a very complicated and sophisticated process which is largely still dependent upon empirical observations and experience (see, e.g., Greenberg et al. col. 1, line 54 to col. 2, line 34). In particular, it can not be theoretically predicted how a specific component of a coating syrup will affect the coating process, in particular its effect upon the recrystallization of the components that are applied to the core, and how this will affect the quality of the coating, the effects on the product due to storage, the product's appearance, its organoleptic properties, and so on (see Greenberg col. 2, lines 34-55).

Firstly, in contrast to the teachings found in Greenberg, applicants' claimed chewing gum contains calcium salts (see, e.g,, those specifically recited in claim 1 as amended) having a low solubility which is significantly below the solubility given for the calcium salts used in the Greenberg process (see, e.g., pp. 10-12 of applicants' Amendment dated September 22, 2008). Applicants respectfully disagree with the statement by the Examiner at p. 7, lines 3-5 of the present Office Action, i.e, that the differences in solubility noted in applicants' prior response are not significant. The solubility according to Greenberg is 5 g/l at 10°C, whereas the solubility of the salts used in forming applicants' claimed chewing gum (i.e., as recited in amended claim 1) is 1 g/l at 20°C. There is, moreover, even more than a 5-fold difference between the value associated with the present invention and than that taught for use in the prior art since the solubility values noted above are given at <u>different temperatures</u> (i.e., 10°C for the reference versus 20°C in the case of applicants' chewing gum), and it is well known to those of even ordinary skill in this field of art that as the temperature is increased, the solubility is dramatically increased .

Secondly, applicants note that the coating material claimed for use in the present invention (i.e., as recited in claim 1) is a <u>composite material</u> comprising a protein component together with the calcium salt. Thus, the teaching referred to above regarding solubility concerns a coating layer which not only includes a calcium salt which is much less soluble than the calcium salts described in Greenberg, but which, as recited in applicants' claim 1, is additionally combined with a protein component to form a composite. Greenberg, on the other hand, does not

teach, or even suggest, the use of a protein component in the coating of a chewing gum. Greenberg, moreover, does not disclose using such a composite material comprised of a protein material and a calcium salt to comprise a coating layer.

One having an ordinary level of skill in this field, taking the above-identified distinctions in the coating process as taught in Greenberg versus the process used in forming applicants' claimed chewing gum into account, would not find it 'obvious' to employ the slightly-soluble calcium salts recited for use in applicants' claims for at least the reasons set forth in applicants' previous response (dated September 22, 2008) filed in this application. In addition, such individual would also not find it obvious to also employ protein-containing composites in such a coating process in that proteins are not conventional components in coating layers of chewing gums, or in processes for applying such coating layers. In fact, as indicated above the Greenberg reference contains no disclosure regarding the use of protein components in a gum-coating layer. This is not surprising since such protein components are known by those having ordinary skill in this art to soak up water, to negatively affect the crystallization of the sweetener which is to be crystallized out on the gum core, and to cause agglomeration problems, i.e., the sticking together of the coating components during the coating process and also the sticking of the coating material to the coating drum - as well as the core to be coated.

There was, thus, a great deal of prejudice exhibited in the prior art against the use of protein compounds during the recrystallization of carbohydrates, in particular in the coating of cores and, even more particularly, in the coating of chewing gum cores. Thus, those having an ordinary level of skill in this art were not at all motivated to employ a composite material, according to the disclosure of Kropf, in the system taught for use in Greenberg. Applicants submit that the prior art provides no motivation to overcome the above-described prejudice. That is, applicants respectfully submit that the teachings contained in the cited prior art would not suggest to one having an ordinary level of skill in this art to use a protein component in the indicated coating process with a reasonable expectation of resulting in the production of a successful coating.

Further to the above, also in view of the low solubility of the calcium salt and the properties described herein of the protein component, applicants submit that the skilled artisan

would not have found it obvious to combine the teachings of Kropf and Greenberg, which as indicated above, stand in sharp contrast to each other. More particularly, Kropf teaches to employ a composite material in a relatively technically simple system which does not require a crystallization step, in particular not a controlled crystallization of any of the components and, even more particular, without a crystallization of carbohydrates. On the contrary, Greenberg does disclose a significantly more complex system which requires a controlled recrystallization of carbohydrates from a coating syrup applied to the core to form the coating layer. Both the slightly (i.e., poorly) water-soluble calcium salts and the protein component taught for use in forming the coating layer of the chewing gum according to, e.g, claim 1, as well as composites formed of these two materials, were not viewed by those having an ordinary level of skill in this field at the time the present invention was made as being useful in a recrystallization process as now used in forming the applicants' coated chewing gum. Applicants, however, obtained surprisingly unexpected results using the specific slightly water-soluble calcium salts now recited in claim 1 in combination with; a protein component and thereby producing a composite useful, despite the prejudices inherent in the teachings of the prior art, for forming an acceptable coating of a chewing gum, the advantages of which are as set forth on pp. 6-8 of applicants' specification.

Additionally, there is no reasoning or motivation exhibited in the prior art cited to reject applicants' claims for one having an ordinary level of skill in this field to employ the composite described in the art in the coating of a chewing gum, rather than in its center. That is, a consideration by a skilled artisan of the specific recrystallization difficulties inherent in the methodology disclosed for use in the prior art would in applicants' view, rather, have led such a skilled individual more towards using the composite in the gum center, rather than in the coating, due to the problems inherent (as described above) in using it in such coating. This is due to the fact that the gum center is much easier to produce than the coating layers since there is no need in producing the center for the repeated recrystallization and drying steps required in producing the coating layers.

Based on the reasons presented above, the Examiner is respectfully requested to reconsider and withdraw the rejections of applicants' claims under 35 U.S.C. §103 and to issue a Notice of Allowance for all of the claims of this application.

Respectfully submitted,

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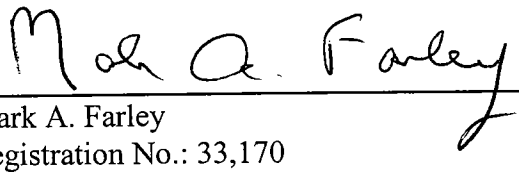

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